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510(k) Premarket Notification
Combilines™ Hemodialysis Blood Tubing Set
Transducer Protector

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510 (k) Summary

Submitter Name: Fresenius Medical Care North America
Two Ledgemont Center
95 Hayden Avenue
Lexington, MA 02420

Contact Name: Arthur E. Eilinsfeld
Director, Fresenius Regulatory Affairs
Telephone: 781-402-9068
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Date of Summary: February 25, 2000

Trade Name: Combilines™ Hemodialysis Blood Tubing Set
Transducer Protectors

Common Name: Transducer protectors

Classification Name: Hemodialysis System and Accessories

Substantial Equivalence Claim: Substantial equivalence for the design and construction of the Borla TP as a kit ALTERNATE VENDED COMPONENT, is claimed to the Haemotronic TP [510(k) number K900841, May 15, 1990] predicate device. For the substantially equivalence of the VIRAL RETENTIVE claim for both the proposed Borla TP and the current Haemotronic TP kit components, the Medisystems Transducer Protectors [510(k) number K983076, November 25, 1998] is the predicate device.

Device Description: Combilines™ Transducer Protectors are designed to be used as protective devices for pressure monitors as well as to help maintain the sterility of the blood tubing fluid pathway. The 0.2µm hydrophobic membrane helps prevent cross-contamination by viruses, bacteria and particulate matter while preventing the flow of fluids to the hemodialysis machine pressure monitor.

Statement of Intended Use: Combilines™ Transducer Protectors are single use, disposable, prescription devices intended for use as protective devices for pressure monitors and to help protect the sterility of the fluid pathway. This is identical to the intended use of the legally marketed predicate device.

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510 (k) Summary (continued)

Discussion of Technological Characteristics: The technical characteristics of the device consist of a filter housing that contains a 0.2 μm hydrophobic membrane. The combination of the pore size and hydrophobic nature of the membrane prevents the flow of fluids, viruses, bacteria, and particulate matter into the pressure monitor at pressures lower than the rated pressure of the device.

Safety and Effectiveness: To assure that the device is safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes sterility, functional testing* visual inspection, pyrogenicity*, and dimensional inspection.

* Vendor certified

Arthur Eilinsfeld
Director, Fresenius Regulatory Affairs

2/29/00
Date

Premarket Notification 510 (k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2000

Mr. Arthur Eilinsfeld
Director of Regulatory Affairs
Fresenius Medical Care North America
Dialysis Products Division
Two Ledgemont Center
95 Hayden Avenue
Lexington, MA 02420

Re: K000702
Combilines™ Hemodialysis Blood Tubing Set
Transducer Protectors
Dated: May 23, 2000
Received: May 25, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FIB and FJK

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Premarket Notification
Combilines™ Hemodialysis Blood Tubing Set
Transducer Protector

Indications for Use Statement

Device Name:

Combilines™ Hemodialysis Blood Tubing Set Transducer Protectors

Indications for Use:

The Fresenius Combilines™ Hemodialysis Blood Tubing Set Transducer Protectors are single use, disposable, prescription devices intended for use as protective devices for pressure monitors on hemodialysis machines, as well as to help protect the sterility of the blood tubing fluid pathway. The filter helps prevent cross-contamination by viruses, bacteria, and other particulate matter while preventing the flow of fluids to the hemodialysis machine's pressure transducer.

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000702